K071676 (p1 of 2)

Exactech® Novation Crown Cup™ Constrained Liners and Rings
Special 510(k) - 510(k) Summary

Trade or proprietary or model name(s):
Novation Crown Cup™ Constrained Liners and Rings

JUL 19 2007

Common Name
Constrained Liners and Rings

Classification name
Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR Section 888.3310)

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
#K040601	AcuMatch A-Series & MCS Constrained Liners	Exactech, Inc.

Indications for Use:

Novation Crown Cup™ Constrained Liners and Rings are components of the Exactech Novation® non-cemented acetabular cup system. The device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. They are intended for press-fit fixation and are compatible with Exactech press-fit or cemented femoral stem components.

Device Description:

The proposed Novation® Constrained Acetabular Liners are modifications of the previously cleared AcuMatch A-Series predicates. The design features of the subject devices are summarized below:

NOVATION CONSTRAINED LINERS

- Sphere and taper inner diameter geometry for compatibility with the Novation Crown Cup
- Increased range-of-motion and lever-out moment by decreasing the height of the constraining petals, increasing the constraining diameter and increasing the lead in chamfer
- Addition of a 36mm ID option.

NOVATION CONSTRAINED RINGS

- The constraining ring will be made of Ti-6Al-4V per ASTM F1472 instead of Ti-6Al-4V per ASTM F136.

- Ring snaps into a locking feature on the Novation Crown Cup instead of press-fit.
- Inner and outer diameter of the constraining ring modified for compatibility with the proposed constrained liner and Novation Crown Cup.

Substantial Equivalency Conclusion:

Engineering evaluations were conducted to verify that the performance of the proposed acetabular components would be adequate for anticipated *in vivo* use. Based on successful results discussed in this submission, we conclude that the proposed devices are substantially equivalent to the previously cleared predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Exactech, Inc.
% Mr. Graham Cuthbert
Regulatory Affairs Specialist
2320 NW 66th Court
Gainesville, Florida 32653

JUL 19 2007

Re: K071676
Trade/Device Name: Novation Crown Cup™ Constrained Liners and Rings
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWZ
Dated: June 15, 2007
Received: June 19, 2007

Dear Mr. Cuthbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Novation Crown Cup ™ Constrained Liners and Rings
Special 510(k) – Indications for Use

510(k) Number: K071676

Device Name: **Exactech Novation Crown Cup ™ Constrained Liners and Rings**

Intended Use: Exactech Novation Crown Cup ™ Constrained Liners and Rings are components of the Exactech Novation® non-cemented acetabular cup system. The device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. They are intended for press-fit fixation and are compatible with Exactech press-fit or cemented femoral stem components.

Prescription Use X **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carlene Brenner

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071676